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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/831,669	05/11/2001	Steven Powell	00362-03	8410

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UNIVERSITY OF VIRGINIA PATENT FOUNDATION
1224 WEST MAIN STREET, SUITE 1-110
CHARLOTTESVILLE, VA 22903

EXAMINER

SHEINBERG, MONIKA B

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 01/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/831,669

Applicant(s)

POWELL ET AL.

Examiner

Monika B Sheinberg

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 October 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) 11-13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 and 14-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-17 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION***Election/Restrictions***

Applicants' election with traverse of Group III (claims 14-17) in Paper No. 7, filed 11 October 2002 is acknowledged. The traversal is on the ground(s) that Groups I (claims 1-7) and Group III are directed to identical subject matter in which one group has additional steps over the other. Applicants' arguments are persuasive for the consolidation of Groups I and III, thus claims 1-7 and 14-17. Examiner would like to further include claims 8-10 due to the method of these claims also adds an additional step of amplification while still pertaining to the same subject matter and retaining the same steps as seen in claim 14. The kit of claims 11-13, directed to stool analysis, is distinct in that it is a mere stool analysis kit that does not require the steps of methodology as disclosed for the method claims 1-10 and 14-17.

Thus claims 11-13 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement with regards to the claims of Group II (claims 8-13), there is no response to the lack of arguments. Applicants' timely traversed the restriction (election) requirement in Paper No. 7.

Claims 1-10 and 14-17 have been examined.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-10 and 15-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite for failing to recite a final process step which agrees back with the preamble. While minor details are not required in method/process claims, at least the basic steps must be recited in a positive, active fashion. For example, claim 1 is drawn to a method for

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isolating amplifiable nucleic acids, yet the claim recites a final step nucleic acid recovery without any indication of amplification. The claims do not set forth the conditions/state when the method has "isolated amplifiable nucleic acids". As such claims 2-7 are also indefinite due to their dependency from claims 1.

Claims 1 and 14 recites the limitation "said stool sample" in lines 3. There is insufficient antecedent basis for this limitation in the claim, while there is antecedent basis for "a solid stool sample" (lines 1). As such claims 2-7 and 15-17 are also indefinite due to their dependency from claims 1 and 14 respectively.

The term "about" in claims 1 and 14 (lines 5 and 10 respectively), is a relative term which renders the claim indefinite. The term "about" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is unclear as to the amount of degrees below 90°C applicable in addition to the amount of degrees above 100°C is applicable to the range of temperature for the instant claims. As such claims 2-7 and 15-17 are also indefinite due to their dependency from claims 1 and 14 respectively.

The term "about" in claims 3, 4, 8, 14 and 16 in regard to the centrifuge speed, is a relative term which renders the claim indefinite. The term "about" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is unclear as to actual limitations of the range of speeds applicable to centrifugation. For example it is uncertain to what range below 400g or above 500g as is required by claim 3; or below 2000g or above 2200g as is required by claim 4. As such claims 5-7, 9, 10, 15 and 17 are also indefinite due to their dependency from the indefinite claims 3, 4, 8, 14 and 16.

Claims 3 and 16 are vague and indefinite due to the lack of units of the centrifugal force "400" as seen for example, in line 2 of claim 3. As such claims 4-7 and 17 are also indefinite due to their dependency from the indefinite claims 3 and 16.

Claims 4, 8 and 14 are vague and indefinite due to the lack of units of the centrifugal force "2000" as seen for example, in line 4 of claim 4. As such claims 5-7, 9, 10 and 15-17 are also indefinite due to their dependency from the indefinite claims 3 and 16.

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-3 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Makristathis et al. (*J. Clin. Microbiol.*, Sept. 1998) in view of Coll et al. (*J. Clin. Microbiol.*, Oct. 1989).

Makristathis et al. teaches a method of detecting *Helicobacter pylori* in stool samples by a highly sensitive PCR analysis of the extracted and purified amplifiable nucleic acids (abstract). The reference teaches the boiling (p. 2772, 2nd column, line 3) a stool sample in a lysis buffer containing chaotropic agents (as defined by the specification on page 6, lines 12-16) such as the chelator EDTA and a detergent of Tween and TritonX (1st column, 2nd paragraph). Makristathis et al. further separates the lysed cell solution by centrifugation. The solution is then treated with RNase A and proteinase K (as required by claims 1 and 2), and followed by phenol-chloroform-isoamylalcohol extractions; wherein the nucleic acids are recovered for amplification.

Makristathis et al. does not teach a slow spin after the heating step of claim 1 (required by claim 3); nor the use of 8.0M urea (required by claim 7).

Coll et al. teaches a method of nucleic acid extraction and purification from stool samples in which a spin of 750g (p. 2246, lines 10-11) was performed after heating a lysed cell solution that included 8.0M of urea and the detergent 0.25% sodium dodecyl sulfate (lines 6-7).

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Thus, it would have been obvious to one of ordinary skill in the art at the time of the invention was made to perform the nucleic acid extraction and purification method of Makristathis et al. and further modify the lysis solution to include urea in addition to modifying the centrifugal speed as per the teachings of Coll et al. Thus, one of ordinary skill in the art would have been motivated to do the modifications to the extraction method in order "maximize recovery" of the favored nucleic acid (Coll et al. p. 2247, 2nd column, 3rd paragraph) for a cleaner sample for the sensitive PCR assay of Makristathis et al.

Conclusion

No claim is allowed.

Inquiries

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Monika B. Sheinberg, whose telephone number is (703) 306-0511. The examiner can normally be reached on Monday-Friday from 1 P.M. to 8 P.M. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Patent Analyst, Chantae Dessau, whose telephone number is (703) 605-1237, or to the Technical Center receptionist whose telephone number is (703) 308-0196.

December 30, 2002

Monika B. Sheinberg
Art Unit 1634

MBS

S. Zitomer
STEPHANIE W. ZITOMER
PRIMARY EXAMINER